REMARKS

Claims 1-10 have been cancelled herein. The cancellation is without prejudice on the merits. Claims 11-36 are newly added herein. No new matter is added and no new issues for search or consideration are introduced. Favorable reconsideration is respectfully requested.

Applicant's undersigned counsel thanks Examiner Scheiner for indicating that Claims 2 and 6 contain allowable subject matter. In this amendment, the subject matter of these two claims has been recast as independent Claims 35 and 36. Claims 35 and 36 incorporate the subject matter of former Claims 2 and 6 (respectively), any intervening dependent claims, and the base claim. Applicants thus submit that Claims 35 and 36 are now allowable.

Independent Claim 11 (previously Claim 1, relating to a method for diagnosing spongiform disease or demyelinating disease) and independent Claim 24 (previously Claim 8, relating to a diagnostic kit for the detection of spongiform disease or demyelinating disease) have been added. Claim 11 includes assaying for at least two types of antibody out of a possible three. These three types of antibody are:

- antibodies which bind to myelin, or to one or more antigenic parts thereof;
- antibodies which bind to neurofilaments, or to one or more antigenic parts thereof; and
- antibodies which bind to an Acinetobacter species that presents to the vertebrate an antigen that mimics the myelin of the vertebrate.

New Claim 24 has been similarly amended to include as the test antigens at least two antigens selected from isolated myelin, isolated neurofilaments, and an isoalted antigen specific for antibodies to an Acinetobacter species containing a peptide sequence that mimics the myelin of the vertebrate.

New dependent Claims 12 and 25 have been added specifying that the Acinetobacter contains the sequence ISRFAWGEV. Support for this can be found in WO 98/13694 and WO 99/47932, which are incorporated in the present application by reference (see page 1).

Previous dependent Claim 5 (new Claim 14) and previous dependent Claim 9 (new Claim 31) have been amended to clarify that the specific sequences are antigens for

the assaying of antibodies to neurofilaments. Support for this amendment can be found on page 2 lines 26 to 30 of the application as filed.

New dependent Claim 15 has been added. This claim relates to a preferred embodiment of the invention wherein the method includes an assay for antibodies which bind to an Acinetobacter species that presents to the vertebrate an antigen which exhibits molecular mimicry with the myelin of the vertebrate. Support for this can be found on page 5 of the application as filed.

New dependent Claims 16 to 18 and 27 to 29 have been added. These more specifically define part (c) of the independent claims.

New dependent Claims 19 to 22 have been added. Support for these is found on page 5, lines 10 to 29 of the application as filed.

New kit Claim 26, relating to a preferred embodiment where the Acinetobacter species is Acinetobacter calcoaceticus, has been added. Support for this claim can be found on page 1 line 17, referring to WO 98/13694, which is incorporated into the present application by reference, and on page 2, line 5, and on page 5, line 8.

New kit Claim 32, which corresponds to the previous method Claim 2 (new method Claim 13) has been added.

New kit Claims 30, 33 and 34, relating to preferred embodiments in which the kit contains antigens for all three types of antibody, has been added. Support for these claims can be found on page 5 of the application as filed.

Previous Claims 3, 4 and 6 have been deleted.

The following remarks address the issues presented in the Office Action in order of their appearance.

Objections to Claims 1 and 7:

The objections to Claims 1 and 7 have been rendered moot by cancellation of the claims. However, in the claims newly added in this amendment, the Examiner's recommendations have been incorporated.

Rejection of Claims 8 and 10 Under 35 USC §101:

This rejection has been rendered moot by cancellation of the claims. In new Claim 24, however, the Examiner's recommendations have been incorporated into the claim. Specifically, the various antigens are noted as being isolated and the claim includes a recitation that the antigens are disposed in a suitable container.

Rejection of Claims 5 and 8-10 Under 35 USC §112, Second Paragraph:

This rejection has been rendered moot by cancellation of the claims. In new Claim 24, however, the Examiner's recommendations have been incorporated into the claim. Specifically, the various components are noted as being disposed in a suitable container.

Rejection of Claims 1, 3, 4, and 7 Under 35 USC §102(b) in View of Ebringer et al. (11/1997) Environmental Health Perspectives 105(11):1172-1174 or Ebringer WO 98/13694):

This rejection has been rendered moot by cancellation of the claims.

As potentially applied to the claims newly submitted with this amendment, this rejection is believed to be in applicable. As stated above, Claim 11 is limited to a method of assaying for at least two of the three listed types of antibodies. The presently recited method is thus limited to the selection of two out of a total of three types of antibodies: antibodies to myelin, antibodies to neurofilaments, and antibodies to Acinetobacter. Any two of these three (or all three) can be assayed to give the most accurate indication of the presence of the recited diseases.

In the preferred embodiment of the invention, a combination of all three antibodies will be used. However, it is also within the scope of Claim 11 to select any two antibodies to be assayed (which greatly improves the specificity of the claimed diagnostic method over the assaying for antibodies to Acinetobacter alone).

In making this rejection, the Office relies upon Ebringer et al. (1997) and WO 98/13694. (Ebringer et al. (1997) is a scientific literature counterpart to the WO 98/13694 publication). Both of these documents result from the work of the present Applicant. The Office assumes that assaying an antibody which binds to Acinetobacter also assays

antibodies which bind myelin or an antigenic peptide that exhibits molecular mimicry of a mammalian myelin peptide, due to cross-reactivity. The assumption, however, is incorrect. As emphasized in the Response to the Written Opinion filed during the international phase (copy enclosed), the present invention relies on **separate** measurements of antibodies to myelin, neurofilaments, and Acinetobacter (see page 5, line 6 of the application as filed).

Moreover, as stated above, assaying more than one type of antibody greatly improves the specificity of the diagnostic method over the assaying for antibodies to Acinetobacter alone (as disclosed in the cited documents). Neither of the cited documents suggests or hints at the possibility of a diagnostic test using the materials positively recited in Claim 11. It was not within the foresight of even the present inventor to propose the claimed method. This being despite the fact that he is the champion of the theory of a molecular mimicry mechanism underlying these diseases. (Applicant's counsel notes for the record that the actual mechanism by which the claimed invention functions is irrelevant to its patentability.)

In short, the two Ebringer references neither disclose nor suggest the invention positively recited in Claim 11. Applicant therefore submits that Claim 11 and the claims dependent thereon are both novel and unobvious in view of the prior art now of record.

For the reasons given above, independent kit claim 14 (previous claim 8) has also been limited such that the kit comprises, as test antigens at least two of myelin, neurofilaments and an antigen specific for antibodies to Acinetobacter.

Errata:

Regarding the term "myelin neurofilaments," the incorrect term "myelin neurofilaments" was used by oversight in the PCT application as originally filed. During the course of the international examination, this term was replaced by the proper term "neurofilaments" on the ground that it would have been clear to the skilled person as to what was intended in the light of the document as a whole. An explanation was supplied to the Examining Authority in the Response to the Written Opinion (attached hereto) to show that this change of wording was supported by certain passages in the original text.

It is generally known to those skilled in the medical arts that neurofilaments are structural components that constitute part of the axonal cytoskelton. Although neurofilaments in the brain are insulated by a myelin sheath, the neurofilaments are not part of myelin itself. The term "myelin neurofilaments" would therefore be recognized as mistaken terminology and not as indicating a specific sub-class of neurofilaments. When axons are demyelinated, the neurofilaments are exposed and induce antibodies. Axonal diameter is believed to be related to the number of neurofilaments and their state of phosphorylation.

CONCLUSION

Applicants submit that the application is now in condition for allowance. Early notification of such action is earnestly solicited.

Respectfully submitted,

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